

**JULY 12, 2016
COMAR REVISIONS 10.62.01-35
(VERSION 3)**

Chapter	Chapter Title	Section #	Proposed Revision	Explanation
.01	Definitions	(35)(b)	Change “?” to Greek symbol for Delta	Fixes a typographical error.
		(24a)	“(24a) “Processor agent” means an owner, an employee, a volunteer, an officer, or a director of a licensed processor.”	Adds a missing definition.
.08	Medical Cannabis Grower License	.03	Strike out the text of .03 and insert “A. Each individual listed in the application addenda in Regulation .02C(1) and (2) shall: (1) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigation; (2) Pay the fee authorized under Criminal Procedure Article, § 10-221(B)(7), Annotated Code of Maryland for access to State criminal history and records; and (3) Request that the individual’s state and national criminal history record information be forwarded to the Commission. B. The applicant shall notify the Commission each individual listed in the application addenda in Regulation .02B(1) and (2) has completed this requirement.”	This amendment fixes the problem in our regulations regarding an outmoded reference to how fingerprint specimens are obtained for criminal history record checks.
		.05F	Strike out “suspended.” and insert “withdrawn.”	Fixes an ambiguity if applicant does not provide requested information on a timely basis. “Suspended” implies suspended for a time period, but that was never specified. “Withdrawn” expresses our original intent.

		.05I(6)(d) (ii)	Strike out “strain” and insert “variety”	“Strain” was a term in an early draft of the regulations that the Commission replaced with “variety.” This amendment corrects a word substitution that should have been made in 2015.
		.06D	Before “Within” insert “(1)”. At the end insert “(2) The applicant shall submit both the stage 2 application fee and the annual license fee appropriate for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(1), to the Commission by 4 p.m. of the fourteenth business day following the issuance of the Commission’s notification.”	This amendment clarifies precisely when the stage 2 and annual license fees should be paid. It anticipates that most pre-approvals will be issued a license and provides expedited payment of annual license fee, a key part of the commission’s funding stream that is dependent wholly on license fees. (If the license is not ultimately issued, the fee is fully refunded, see new .07D below.)
		Rewrite .07 Issuance of License .07A	Strike out the text of A. and insert “A. After the notification by the Commission and payment of fees under Regulation 10.62.08.06,	This revision clarifies the requirements for financial background information. It eliminates the serious problem of the existing

			<p>(1) If the applicant is an individual, the applicant shall within 90 days, submit to the Commission the appropriate federal tax returns filed by the applicant for the previous three years, and other financial, personal and background information requested by the commission sufficient to establish to the commission the applicant's capacity to operate a licensed medical cannabis growing enterprise and to establish the applicant's good moral character;</p> <p>(2) If the applicant is a corporation that has not been operational for at least one year before the notification, the officers, directors, and investors with 5 percent or more of an investment in the applicant corporation shall, within 90 days, submit to the Commission the appropriate federal tax returns filed for the previous three years they each have filed, and other financial, personal and background information requested by the commission sufficient to establish to the commission the capacity of the owners, officers and directors of the applicant corporation to operate a licensed medical cannabis growing enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation; or</p> <p>(3) If the applicant is a corporation that has been operational for at least one year before the notification, the applicant shall, within 90 days, submit to the Commission an audited financial statement, and the officers, directors, and investors with 5 percent or more of an investment in the applicant corporation shall, within 90 days, submit to the Commission the appropriate federal tax returns filed for the previous three years they each have filed, and other financial, personal and background information requested by the commission sufficient to establish to the commission the capacity of the owners, officers and directors of the applicant corporation to operate a licensed medical cannabis growing enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation."</p>	<p>regulation that requires "audited financial statements" from businesses with no operational history and from individuals whose finances are not subject to "audited financial statements." The individuals who would need to provide in-depth financial backgrounds would only be the officers, directors and investors with 5 percent or more of an investment in the applicant corporation. The amendment categorizes applicants in three ways: individuals, new businesses, and businesses that have been operational for at least a year.</p>
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		New .07B	Strike out the text of B. and insert “B. (1) The Applicant shall notify the Commission that its premises, procedures, operations and personnel are ready to be inspected in anticipation of the issuance of a license. (2) The Commission shall notify the applicant when it will carry out the pre-licensing inspection. (3) The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that (i) the criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character; (ii) the applicant’s premises are under the legal control of the applicant; (iii) the premises comply with all zoning and planning requirements; (iv) the premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter; (v) the staff are trained and prepared to follow the procedures; and (vi) the procedures for cultivation and inventory control are as specified in the application.	This new subsection clarifies the process for granting a license, and clarifies the general criteria necessary to obtain a license.
		New .07C	“C. Upon the determination that all of inspections demonstrate that the applicant’s entity and facility comply with the regulations, and is ready to commence business in compliance with the regulations and application, and financial and other background investigations have been completed and passed, the Commission may notify the applicant that it has qualified for a license either to grow medical cannabis or to grow medical cannabis and distribute it, and may issue such license.	This new subsection clarifies that that when the inspections and background investigations have been passed, the commission may issue a license.
		New .07D	“D. In the event that the Commission determines to not issue a license, the Commission shall refund the annual license fee promptly.”	This new subsection clarifies that if an applicant who has paid the annual fee before the final inspection is not granted a license, the annual fee shall be promptly refunded.
.09	Medical Cannabis	.03B(2)	Strike out “Registry” and insert “Repository”	Technical change

	Grower Agent			
.12	Inventory Control by Grower	.02A	Strike out A and insert the following: "A. A licensee shall use a perpetual inventory control system as approved by the Commission that identifies and tracks the licensee's stock of medical cannabis from the time the medical cannabis is propagated from seed or cutting to the time it is delivered to a licensed dispensary, licensed processor, independent testing laboratory, or a qualifying patient or caregiver."	Clarifies that the inventory control system shall include the Commission-approved system.
.15	Medical Cannabis Grower Quality Control	.04A	Strike out A and insert "That is registered by the Commission;"	Simplifies that the independent testing laboratory used by the grower must simply be one that is registered with the commission.
		.05A	Strike out the text of A up through the colon and substitute-- "A. The percentage by weight of each of the following compounds that are present in the batch, and whether the percentage by weight for each of the following compounds conforms to the specifications for the variety:	Clarifies how the certificate of analysis should identify the presence of specific cannabinoid compounds.
		.05B	Strike out "required" and insert "specified" in lieu thereof.	Clarifies that the certificate of analysis must report that the presence of contaminants does not exceed the specifications of the AHP monograph.
		NEW .05C	"C. To the Commission each instance in which the batch is out of compliance with the specification for the batch."	Requires the Independent testing laboratory to forward to the commission a certificate of analysis whenever the

		.06A	<p>Strike out A through the colon and substitute:</p> <p>"A. If the certificate of analysis for the batch indicates the levels of Δ 9-Tetrahydrocannabinol (THC), Tetrahydrocannabinolic Acid (THCA), Cannabidiol (CBD), Cannabidiolic Acid (CBDA), and other active ingredients as determined by the Commission present in the batch conform to the specifications for the variety, the license grower may:"</p>	<p>analysis reveals the batch is out of compliance with specification for the tested batch.</p> <p>Clarifies a batch may be released for distribution only if the certificate of analysis reports that the identified cannabinoids present in the batch conform to the specifications for the variety.</p>
		.07A	<p>Strike out .07A through the colon, and substitute</p> <p>" A. The independent testing laboratory shall obtain from each batch from each licensed grower, by means of an appropriate sampling technique, a sufficient number of samples to perform tests for product stability at 6-month intervals to:</p>	<p>Clarifies the procedure to be followed to obtain samples for support of the stability testing</p>
		.07B	<p>Strike out .07B through the colon, and substitute</p> <p>"B. The independent testing laboratory shall obtain from each batch from each licensed grower, by means of an appropriate sampling technique, a sufficient number of samples to be available for (1) testing of the batch in the event follow-up testing is necessary after an adverse reaction report or other matter; and (2) to retain such samples for one year past the date of expiration of the batch.</p>	<p>Clarifies that the responsibility to obtain and retain samples to test in event of suspected problems with a batch lies with the independent testing laboratory.</p>
.16	Independent Testing Laboratory Registration	.01B(1)	Delete "a non-profit," and insert "an"	Recognizes that highly regarded accreditation bodies may be "for-profit" corporation as well as

				<p>“non-profit,” and eliminates the mistaken preference for “non-profit” only.</p> <p>Inserts an inadvertently omitted descriptor.</p> <p>Corrects word</p> <p>Inserts word inadvertently omitted.</p> <p>Reorganizes the order of existing criteria.</p> <p>Provides that only one of two possible accreditation requirements is necessary for provisional registration of an independent testing laboratory.</p> <p>Provides that Independent testing laboratory inventory controls need to conform to Commission’s inventory tracking system.</p>
		.01B(1)	Insert “ISO/IEC” before 17025	
		.01B(2)	Strike “accrediting” and insert “accreditation”	
		.02C(1)	Insert “testing” after “independent”	
		New .02C(3)-(6)	<p>“(3) Submits evidence that the premises of the independent testing laboratory comply with all zoning and planning requirements;”</p> <p>(4) Submits the name, address, and date of birth and Social Security Number of each independent testing laboratory employee and a copy of the application form completed by each independent testing laboratory employee; and</p> <p>(5) Submits a copy of the contract with the accreditation body by which the independent testing laboratory is applying to become accredited accompanied by a copy of the proposed scope of the accreditation; or</p> <p>(6) Submits evidence that the independent testing laboratory has been accredited by an accreditation body in another jurisdiction and a copy of the scope of the accreditation.”</p>	
		.05D	Strike existing .05D and substitute “D. Has established standard operating procedures, in conformity with the Commission’s seed to sale inventory tracking system, to provide for adequate chain of custody controls for samples it has obtained.”	

.19	Medical Cannabis Processor License	.02F	Strike out the text of F. and insert “F. (1) Each individual listed in the application addenda in Regulation .02B(1) and (2) of this chapter shall: (i) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigation; (ii) Pay the fee authorized under Criminal Procedure Article, § 10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records; and (iii) Request that the individual’s state and national criminal history record information be forwarded to the Commission. (2) The applicant shall notify the Commission once each individual listed in the application addenda in Regulation .02B(1) and (2) of this chapter has completed this requirement.”	Corrects fingerprint specimen format
		.04F	Strike out “suspended.” and insert “withdrawn.”	Fixes an ambiguity if applicant does not provide requested information on a timely basis. “Suspended” implies suspended for a time period, but that was never specified. “Withdrawn” expresses our original intent.
		.05D	Before “Within” insert “(1)”. At the end insert “(2) The applicant shall submit both the stage 2 application fee and the annual license fee for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(3), to the Commission by 4 p.m. of the fourteenth business day following the issuance of the Commission’s notification.”	This amendment clarifies precisely when the stage 2 and annual license fees should be paid. It anticipates that most pre-approvals will be issued a license and provides expedited payment of annual license fee, a key part of the commission’s

		.06A	<p>Strike out the text of A. and insert</p> <p>“A. After the notification by the Commission and payment of fees under Regulation 10.62.19.05,</p> <p>(1) If the applicant is an individual, the applicant shall within 90 days, submit to the Commission the appropriate federal tax returns filed by the applicant for the previous three years, and other financial, personal and background information requested by the commission sufficient to establish to the commission the applicant's capacity to operate a licensed medical cannabis processing enterprise and to establish the applicant's good moral character;</p> <p>(2) If the applicant is a corporation that has not been operational for at least one year before the notification, the officers, directors, and investors with 5 percent or more of an investment in the applicant corporation shall, within 90 days, submit to the Commission the appropriate federal tax returns filed for the previous three years they each have filed, and other financial, personal and background information requested by the commission sufficient to establish to the commission the capacity of the owners, officers and directors of the applicant corporation to operate a licensed medical cannabis processing enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation; or</p> <p>(3) If the applicant is a corporation that has been operational for at least</p>	<p>funding stream that is dependent wholly on license fees. (If the license is not ultimately issued, the fee is fully refunded, see new .07D below.)</p> <p>This revision clarifies the requirements for financial background information. It eliminates the serious problem of the existing regulation that requires “audited financial statements” from businesses with no operational history and from individuals whose finances are not subject to “audited financial statements.” The individuals who would need to provide in-depth financial backgrounds would only be the officers, directors and investors with 5 percent or more of an investment in the applicant corporation. The amendment categorizes applicants in three ways: individuals, new businesses, and</p>
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			<p>one year before the notification, the applicant shall, within 90 days, submit to the Commission an audited financial statement, and the officers, directors, and investors with 5 percent or more of an investment in the applicant corporation shall, within 90 days, submit to the Commission the appropriate federal tax returns filed for the previous three years they each have filed, and other financial, personal and background information requested by the commission sufficient to establish to the commission the capacity of the owners, officers and directors of the applicant corporation to operate a licensed medical cannabis processing enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation.”</p>	<p>businesses that have been operational for at least a year.</p>
		.06B.	<p>Strike out the text of B. and insert “B. (1) The Applicant shall notify the Commission that its premises, procedures, operations and personnel are ready to be inspected in anticipation of the issuance of a license. (2) The Commission shall notify the applicant when it will carry out the pre-licensing inspection. (3) The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that (i) the criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character; (ii) the applicant’s premises are under the legal control of the applicant; (iii) the premises comply with all zoning and planning requirements; (iv) the premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .05 of this chapter; (v) the staff are trained and prepared to follow the procedures; and (vi) the procedures for processing and inventory control are as specified in the application.</p>	<p>This new subsection clarifies the process for granting a license, and clarifies the general criteria necessary to obtain a license.</p>
		.06C	<p>“C. Upon the determination that all of inspections demonstrate that the applicant’s entity and facility comply with the regulations, and the applicant is ready to commence business in compliance with the regulations and application, and financial and other background investigations have been completed and passed, the Commission may</p>	<p>This new subsection clarifies that that when the inspections and background investigations have been passed, the</p>

		.06D	<p>notify the applicant that it has qualified for a license to process medical cannabis, and may issue such license.</p> <p>“D. In the event that the Commission determines to not issue a license, the Commission shall refund the annual license fee promptly.”</p>	<p>commission may issue a license.</p> <p>This new subsection clarifies that if an applicant who has paid the annual fee before the final inspection is not granted a license, the annual fee shall be promptly refunded.</p>
.20	Medical Cannabis Processor Agent	.03B(2)	Strike out “Registry” and insert “Repository”	Technical change
.22	Medical Cannabis Processor Operations	.02A(2)	Strike out (2) and insert the following: “(2) Use a perpetual inventory control system as approved by the Commission that identifies and tracks the licensee’s stock of medical cannabis from the time medical cannabis is received by the licensee, through the stages of processing, to the time it is delivered to another licensee, a licensed grower, a licensed dispensary, independent testing laboratory, or a qualifying patient or caregiver; and”	Clarifies that the inventory control system shall include the Commission-approved system.
.25	Medical Cannabis Dispensary License	.03	Strike out the text of .03 and insert “A. Each individual listed in the application addenda in Regulation .02B(1) and (2) shall: (1) Submit to the Director of the Central Repository fingerprint specimens in the format approved by the Director of the Central Repository and the Director of the Federal Bureau of Investigation; (2) Pay the fee authorized under Criminal Procedure Article, § 10-221(B)(7), Annotated Code of Maryland, for access to State criminal history and records; and (3) Request that the individual’s state and national criminal history record information be forwarded to the Commission. B. The applicant shall notify the Commission once each individual listed in the application addenda in Regulation .02B(1) and (2) of this chapter has completed this requirement.”	This amendment fixes the problem in our regulations regarding an outmoded reference to how fingerprint specimens are obtained for criminal history record checks.

		.05F	Strike out “suspended.” and insert “withdrawn.”	Fixes an ambiguity if applicant does not provide requested information on a timely basis. “Suspended” implies suspended for a time period, but that was never specified. “Withdrawn” expresses our original intent.
		.06D	Before “Within” insert “(1)”. At the end insert “(2) The applicant shall submit both the stage 2 application fee and the annual license fee for the license that has been pre-approved, as specified in COMAR 10.62.35.01A(5), to the Commission by 4 p.m. of the fourteenth business day following the issuance of the Commission’s notification.”	This amendment clarifies precisely when the stage 2 and annual license fees should be paid. It anticipates that most pre-approvals will be issued a license and provides expedited payment of annual license fee, a key part of the commission’s funding stream which is dependent wholly on license fees. (If the license is not ultimately issued, the fee is fully refunded, see new .07D below.)
		.07A	Strike out the text of A. and insert “A. After the notification by the Commission and payment of fees under Regulation 10.62.25.06, (1) If the applicant is an individual, the applicant shall within 90 days,	This revision clarifies the requirements for financial background information. It eliminates the serious

			<p>submit to the Commission the appropriate federal tax returns filed by the applicant for the previous three years, and other financial, personal and background information requested by the commission sufficient to establish to the commission the applicant's capacity to operate a licensed medical cannabis dispensary enterprise and to establish the applicant's good moral character;</p> <p>(2) If the applicant is a corporation that has not been operational for at least one year before the notification, the officers, directors, and investors with 5 percent or more of an investment in the applicant corporation shall, within 90 days, submit to the Commission the appropriate federal tax returns filed for the previous three years they each have filed, and other financial, personal and background information requested by the commission sufficient to establish to the commission the capacity of the owners, officers and directors of the applicant corporation to operate a licensed medical cannabis dispensary enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation; or</p> <p>(3) If the applicant is a corporation that has been operational for at least one year before the notification, the applicant shall, within 90 days, submit to the Commission an audited financial statement, and the officers, directors, and investors with 5 percent or more of an investment in the applicant corporation shall, within 90 days, submit to the Commission the appropriate federal tax returns filed for the previous three years they each have filed, and other financial, personal and background information requested by the commission sufficient to establish to the commission the capacity of the owners, officers and directors of the applicant corporation to operate a licensed medical cannabis dispensary enterprise and to establish the good moral character of the owners, officers and directors of the applicant corporation."</p>	<p>problem of the existing regulation that requires "audited financial statements" from businesses with no operational history and from individuals whose finances are not subject to "audited financial statements." The individuals who would need to provide in-depth financial backgrounds would only be the officers, directors and investors with 5 percent or more of an investment in the applicant corporation. The amendment categorizes applicants in three ways: individuals, new businesses, and businesses that have been operational for at least a year.</p>
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		New .07B	Strike out the text of B. and insert “B. (1) The Applicant shall notify the Commission that its premises, procedures, operations and personnel are ready to be inspected in anticipation of the issuance of a license. (2) The Commission shall notify the applicant when it will carry out the pre-licensing inspection. (3) The Commission shall carry out sufficient inspection and background investigation of finances and related matters to determine that (i) the criminal history background check and background investigation reveal no evidence that demonstrates the absence of good moral character; (ii) the applicant’s premises are under the legal control of the applicant; (iii) the premises comply with all zoning and planning requirements; (iv) the premises and specified procedures conform to the specifications of the application as pre-approved pursuant to Regulation .06 of this chapter; (v) the staff are trained and prepared to follow the procedures; and (vi) the procedures for dispensing and inventory control are as specified in the application.	This new subsection clarifies the process for granting a license, and clarifies the general criteria necessary to obtain a license.
		New .07C	“C. Upon the determination that all of inspections demonstrate that the applicant’s entity and facility comply with the regulations, and is ready to commence business in compliance with the regulations and application, and financial and other background investigations have been completed and passed, the Commission may notify the applicant that it has qualified for a license to dispense medical cannabis, and may issue such license.	This new subsection clarifies that that when the inspections and background investigations have been passed, the commission may issue a license.
		New .07D	“D. In the event that the Commission determines to not issue a license, the Commission shall refund the annual license fee promptly.”	This new subsection clarifies that if an applicant who has paid the annual fee before the final inspection is not granted a license, the annual fee shall be promptly refunded.
.26	Registered Dispensary	.03B(2)	Strike our Registry and insert “Repository”	Technical change.

	Agent			
.28	Licensed Dispensary Operations	.02A(2)	Strike out (2) and insert the following: "(2) Use a perpetual inventory control system as approved by the Commission that identifies and tracks the licensee's stock of medical cannabis from the time medical cannabis is received by the licensee to the time it is delivered to another licensee, a licensed grower, a licensed processor, independent testing laboratory, or a qualifying patient or caregiver; and"	Clarifies that the inventory control system shall include the Commission-approved system.

Last edited: 7/07/2016: 1:15pm (EES)